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COMMENTARY

Mitnovetski and Nicol provide a stimulating and thorough discussion of patenting of medical methods of treatment—an area of law that interests patent lawyers, medical practitioners, and the public. However, a consideration of alternative perspectives to their account of the exclusion of medical methods of treatment from patentability undermines the rhetorical force of their conclusion that there are “strong *ordre public* and morality reasons and “generally convenient” reasons to justify the existence of such patents”. I set out below four counter arguments to their claims that could lead to a more balanced consideration of whether medical methods should be patented.

TWO EXAMPLES

Firstly, the patentability of medical methods of treatment cannot be discussed in isolation from the larger current normative debate about the justice of patenting medical technologies. Although much of what the authors discuss is necessarily speculative because it involves patenting inventions that have not previously been patentable, two cases present concrete instances of the impact of granting patent rights on healthcare. The first is the example of Myriad Genetics Inc, Salt Lake City, UT, USA, which has patented the genetic diagnostic test for the BRCA1 and BRCA2 breast cancer mutations in the US and, to a lesser extent, in Europe. It is enforcing its patent rights to require national healthcare systems to pay its highly increased fee to conduct the test in Atlanta, when hospitals can perform the test locally much more cheaply and efficiently. Many, including the Curie Institute, which is spearheading opposition proceedings at the European Patent Office, argue that allowing such technologies to be patented undermines socialised healthcare regimes, inadvertently leading to privatisation and diminished access to healthcare. Many women have not been able to access the test due to its high cost.

A second well known example concerns access in developing countries to life saving drugs that are used to treat and prevent the transmission of diseases, in particular AIDS. One of the most high profile instances of this struggle was the ruling in 2001 by the South African Constitutional Court against the Pharmaceutical Manufacturer's Association, allowing the generic substitution of medicines, parallel importation of patented medicines, and requiring a transparent medicine pricing system in that country.¹ Over 60 developing countries have lobbied for a “public health” necessity exception to the provisions of TRIPS.² TRIPS requires developing countries to adopt a 20 year minimum of patent protection for pharmaceuticals. Such claims against the rigid operation of the patent regime in healthcare matters are supported by the increasingly recognised right to healthcare (included in a wide range of international treaties*, 60 national constitutions,³ and decisions of national courts*) and the evidence that the existence of patent laws often impedes access to vital medicines. Thus there is a growing recognition in the international and domestic context that the patent system may not function well for the equitable and affordable delivery of healthcare goods, and its strict operation may have to be altered by enacting accompanying regulation or changing patent laws themselves. Our available evidence therefore indicates that patenting medical advances often erects formidable barriers to their access, particularly for people in the developing world.

Asserting that the “patenting of such treatment does not decrease the availability of healthcare and does not create new obstacles, different from those already existing in the medical world” adopts a developed world perspective on intellectual property law and the provision of healthcare. It forgets the majority of the world's population living in poverty and subject to the trade whims and norms of developed nations. It also ignores the globalised, harmonised, and international nature of intellectual property law, where local changes in the laws of developed countries have a huge impact on the international content and definition of intellectual property law. Of particular concern is requiring developing countries to adopt standards that may be inappropriate to encourage innovation and development of healthcare technologies at their stage of political, social, and economic development, or pointing out the well known fact that many developed countries adopted patent laws only *after* reaching a certain stage of economic and social development.³ The “consistency and logic of the law” should not prevail over broader distributional and equity concerns.

THE PATENT SYSTEM

The second problem, following from the above, is the palpable lack of proof for and the inherent pro patent focus of the authors' assertions. Patenting is not a right; it is a privilege, a grant of a property and exclusive monopoly right, valid for two decades with potential for international scope and enforcement. The authors' assertions rest on an allocation of risk that places the greatest risk on society rather than on the inventor. As they claim: “While there is no empirical data to prove either of the competing policy, the authors believe that prohibition of medical methods patents *may well* discourage innovation”. They advocate a precautionary principle, which would dictate that in the *absence* of any proof that the patent system does or does not spur innovation, it is safest to patent in order to encourage innovation.

*Including the International Covenant on Economic, Social, and Cultural Rights (Article 12(1)) and the Convention on the Rights of the Child (Article 24). See also regional instruments including the Banjul Charter (Article 17), the European Social Charter (Article 11(3)) and the American Declaration of the Rights and Duties of Man (Article 17).

With respect, this approach seems reckless given the pressing public health and access concerns to medical methods of treatment outlined above. A truly precautionary principle would only grant a 20 year monopoly when it is proven that the patent system does in fact encourage innovation in industry specific fields, particularly in the field of medical methods. This conclusion is supported by the recent report of the Commission on Intellectual Property Rights to the UK government, authored by patent experts from the developed and developing world as well as a Senior Director at Pfizer.⁶ It held that “[p]atenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.”

It has yet to be proved that only patents provide the appropriate incentives, particularly through the promise of compensating for costly R&D, to encourage socially useful innovation across industries, or specifically in the area of medical methods. The correlation between patents, incentives, and innovation is contested and unclear.⁷ The only strong conclusion emerging from the literature is that determining whether patents provide an incentive to innovate depends on a close analysis of industry and country specific factors, looking to such variables as the size of market players, market structure, and the distribution of public and private research costs.⁷ There are powerful arguments that encouraging innovation and technological development may be better served by schemes outside the patent law, including government buyouts, auctions, R&D tax credits,⁸ and investing in education.⁹ There is even evidence that in certain industries (particularly biotechnology) patents are used to slow innovation, by collecting many patents of similar scope to block future discoveries by competitors.^{10 11} My main point is that it is not a truth that patents stimulate invention, particularly in the area of medical methods. To argue persuasively about incentives requires subtle economic analysis of medical treatment innovators that has just not been conducted.

INTERNATIONAL TRENDS

Thirdly, while the economic justifiability of the authors' argument is unknown, the consensus or trend in international law is towards creating or strengthening medical methods exceptions to patentability. This trend is significant in part because of the increasingly globalised nature of intellectual property law discussed above. While Australia has departed from the medical methods exception in the Bristol-Myers case,¹² the most patent friendly country in the world (the United States) has recently legislated its own form of a medical methods exception, and is considering a similar genetic medical tests and procedures exception from patentability. In 1996 the US passed legislation holding that no damages or injunctive relief would be granted against a medical practitioner patent infringer for the patenting of a medical or surgical procedure performed on a body.¹³ Thus, instead of prohibiting the patenting of medical methods, the US limited the enforcement of the patentee's rights. Recently, Democratic Representative Lynn Rivers introduced a Bill entitled the *Genomic Research and Diagnostic Accessibility Act of 2002* into the House of Representatives¹⁴ which would exempt “genetic diagnostic, prognostic, or predictive test[s] or a medical or surgical procedure” from patent infringement remedies against medical practitioners.¹⁵ In fact, the state of the law in Australia is more of an exception, as it is the only common law country in the Commonwealth that clearly does not have some form of a medical treatment exception from patentability and whose Patent Office allows medical treatment patents (unlike New Zealand).

The authors, further, rely on an “historical accident” argument to explain the continued existence of the medical methods exception in UK and then EU law. The authors contend that a legislated medical methods exception arose in both Parliaments from the failure of a British Parliamentary Committee report¹⁶ to accept the comments of some courts and allow the patenting of medical methods. This interpretation is problematic. Firstly, it ignores the primacy of democratically elected parliaments legislating in areas of complex socioeconomic policy, such as healthcare and regulation of technology and innovation. It implicitly asserts the superiority of courts and their decisions in the law making process and negates that a parliamentary committee can, after considering the broad policy implications and public opinion, recommend other than what the judiciary have suggested. Without any proof or basis in legislative records, the authors speculate that without the report Parliament would have allowed medical treatments to be patented. In fact, White asserts there was political pressure at the time of that legislation to curb patenting in the field of medicine.¹⁷

Secondly, the preparatory documents to the European Patenting Convention (EPC) demonstrate that excluding medical methods was the product of a well debated consensus between European states, many of whom, as the authors acknowledge, had medical methods exceptions to patentability in their laws. It was the need to balance these interests, rather than the Banks Committee report, that determined the shape of the medical methods exception.

THE JUSTIFICATION

The fourth point moves from the more general and structural considerations just discussed to the specific nature and justifications for a medical methods exception. Medical methods, as defined by the patent law, form a specialised niche of otherwise patentable medical technologies, such as medical devices (electrocardiograms (ECG), magnetic resonance imaging (MRI) and so on), drugs, and cosmetic treatments. Medical methods are unique because generally they are used directly by doctors in the course of medical treatment and diagnosis. Thus, from a historical analysis as well as from current judicial and political interpretations, the medical methods exception plays an important role in protecting and preserving medical professional solidarity, which arguably leads to high quality medical care and technological progress. The judicial and academic failure to acknowledge this underlying “golden thread” of justification explains many of the inconsistencies and weak arguments in the law that the authors highlight. Debating whether the law should continue to support a medical treatment exception should ask whether our existing patent law most effectively protects the medical profession in providing optimal healthcare. Only by understanding how a medical treatment exception fits in the complex web of trade, health, and professional regulation can one properly assess whether it should be retained or discarded.

The medical exception from patent law arose in the UK in the late 1800s concurrently with the drive to professionalise medicine and at the height of the abuse of the patents regime by dangerous “patent medicines”, although this exception was not recognized by the courts until 1914.¹⁸ Through the 1800s and early 1900s the *BMJ* and the *Lancet* documented the continuing struggle of medical doctors to secure a professional income by controlling medical service provision, training and inventions. Doctors had to be (and be perceived to be) free from the taint of market commerce and trade, in part because of the conflicts of interest this could generate between their financial interests and their patients' interests.^{19 20} However, as these documents also show, professional

self-regulation required a sense of professional solidarity and an image of competence, which led to internal dispute and resolution regimes removed from lawyers. Finally, the medical profession felt that defining best medical knowledge and practice should occur through introduction and vetting at free and open public lectures, collegial training, group discussion, and publication in the profession's journals.

Patenting methods of treatment conflicted with most of these goals. The association of patents with patent medicines undermined medical credibility, and the purpose of patents was clearly trade regulation, profit, and market control. Allowing doctors to patent medical methods could lead to public fights, thus undermining their authority; this justification has prevailed to the present. While patents could disseminate innovation, the medical profession had its own tailored system of information evaluation and delivery. Focusing on medical methods was intentional as they most clearly represented inventions that would be created and applied by doctors, as opposed to pharmaceutical inventions, for example, that would be manufactured by outside firms.²¹ The extent to which this justification remains useful should be discussed in light of the original purposes for its creation, querying whether those original purposes remain valid given the changing structure of the medical profession and healthcare provision, as well as developments in technology.

CONCLUSION

In considering whether methods for medical treatment should be patentable we must look to reality—historical and current, domestic and international—to objectively assess the impact and purposes of patent laws. We must also consider the data and where none exist, proceed very cautiously, particularly where human rights such as the rights to life, health, the rights to the benefits of scientific progress might be affected. Only after careful, contextual, and multiparty discussion and analysis should any alteration in the state of the law even be considered.

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